



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

SERIAL NUMBER	03/450,641	FILING DATE	05/25/95	FIRST NAMED APPLICANT	KOLEN	ATTORNEY DOCKET NO.	11,226,720,000,000
---------------	------------	-------------	----------	-----------------------	-------	---------------------	--------------------

F3M1/0529

TIMOTHY A. FRENCH, ESQ.  
FISH & RICHARDSON P. C.  
225 FRANKLIN STREET  
BOSTON MA 02110-2804

NASEB P EXAMINER	
ART-UNIT 1	PAPER NUMBER
05/29/97 16	

DATE MAILED:

**Please find below a communication from the EXAMINER in charge of this application.**

Commissioner of Patents

# Office Action Summary

Application No.

450641

Applicant(s)

Koten et al

Examiner

Nasser

Group Art Unit

3311

☒ Responsive to communication(s) filed on 10/7/96☐ This action is FINAL.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 8-18 is/are pending in the application.

Of the above, claim(s) is/are withdrawn from consideration.

☐ Claim(s) is/are allowed.☒ Claim(s) 8-18 is/are rejected.☐ Claim(s) is/are objected to.☐ Claims are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on is/are objected to by the Examiner.☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.☐ received in Application No. (Series Code/Serial Number)☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received:

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 13, 15☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 3311

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an enabling description of the claimed invention. The specification fails to teach one skilled in the art how the heat exchanger functions in cooperation with the remaining elements in the invention. In particular, claim 8 recites that the heat exchanger replaces a selected (precise) amount of fluid from the recirculating loop with fluid from the reservoir to achieve a selected temperature in the recirculation loop. It is unclear how this is possible. The fluid in the recirculation loop is flowing through a lossy medium, absorbing heat from the external environment. The rate of heat absorption by the fluid in the recirculation loop will depend on a variety of factors including the ambient temperature, the body temperature, the flow rate, the size of the patient - which is directly correlatable to the amount of surface area of the pad that contacts the patient, and the amount of fluid in circulation, for example. The exact rate is out of control of applicant. Therefore, applicant is purporting to mix a predetermined amount of fluid at a known temperature with an amount of fluid at an unknown temperature to produce a known temperature. This is not possible. Either the amount of fluid must vary to maintain the predetermined temperature or the temperature must vary. In addition, the examiner notes that on page 11, applicant recites that the rate of fluid exchange in the heat exchanger varies. This completely contradicts the claim and the disclosure on page 17, which says that a predetermined fluid amount is added recirculating fluid,

Art Unit: 3311

as if the mixing rate varies, then a predetermined fluid amount is not being replaced. Further, it is unclear what the predetermined amount of fluid replaced is. In order for one skilled in the art to make and use applicant's invention, the amount of fluid to be replaced must be known. Further, it is unclear how the temperature is maintained if the pump is turned off and on to provide tactile stimulation, as it is unclear how any fluid is replaced during these periods (note that page 17 recites that fluid is constantly replaced). Clarification is required.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the claimed invention. Claim 18 recites that the thermistors are positioned such that one is in the fluid entry tube and one in the fluid return tube. However, on page 14, the last two lines recite that the thermistors are located both in tube 11, which is the fluid entry tube. Therefore, claim 18 lacks a written description in the specification.

Claims 8-18 are rejected as being based on a disclosure objected to under 35 U.S.C. § 112, first paragraph.

No art as intended to be applied to claims 8-18 in that it is unclear exactly how applicant's device functions. Therefore, the scope of the claim is unclear and no meaningful opinion regarding the art could be formed.

Applicant's arguments filed October 7, 1996 have been fully considered but they are not persuasive.

The examiner notes that the art rejection has been withdrawn pending the resolution of the objections to the specification.

Art Unit: 3311

In addition, applicant's comments concerning the clarity of the operation of the heat exchanger have been explained in detail above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Nasser whose telephone number is (703) 308-3251. The examiner's normal work schedule is Monday to Friday, 8:30 to 6:00, with alternate Fridays off.

Alternatively, if the examiner is unavailable, questions may be directed to Jennifer Bahr, the Supervisory Patent Examiner for art unit 3311 at (703) 308-1066. In addition, the group fax number is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

*Robert S. Nasser J.*  
**ROBERT L. NASSER**  
**PRIMARY EXAMINER**

RLN  
May 23, 1997